Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Comparing the efficacy of potassium-enriched salt substitutes versus sodium salt on blood pressure control in patients with hypertension: a double-blind randomized clinical trial.

Protocol summary

Study aim

the effect of potassium-enriched salt substitute compared to sodium salt on blood pressure control in hypertensive patients

Design

A double-blind, randomized, controlled, parallel-group, phase three clinical trial of 500 patients.

Settings and conduct

In this double-blind randomized clinical trial, patients with first and second-stage hypertension. Participants are selected through the available sampling method from the health promotion and prevention center of Rajai Hospital in Alborz. The individuals undergo a six-month follow-up period and are randomized into two groups using the block randomization method. One group receives salt replacement, while the other is given normal salt. blinding is implemented for both patients and outcome assessors

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Participants with first or second-stage hypertension diagnosed by a physician or under treatment with antihypertensive medication are included in the study. Only those individuals who primarily consume homemade meals are eligible to participate in the study. Exclusion Criteria: patients or their family members using potassium-sparing diuretics, potassium supplements, or those with known acute or chronic kidney disease (CKD) will be excluded from participation in this study.

Intervention groups

Intervention group: The salt substitute intervention comprises a blend of 70% sodium and 30% potassium chloride. Control group: Participants in the control group received regular salt (100% sodium chloride)

Main outcome variables

The primary outcome of the study focuses on systolic and diastolic blood pressure. Secondary outcomes encompass 24-hour urinary sodium and potassium excretion, urinary sodium-to-potassium ratio, creatinine levels and attitudes toward the use of salt or salt substitutes.

General information

Reason for update

New changes have been made due to the comments of the reviewers of the journal to which we submitted the protocol article.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240121060757N1**
Registration date: **2024-02-17, 1402/11/28**
Registration timing: **prospective**

Last update: **2025-04-08, 1404/01/19**
Update count: **2**

Registration date

2024-02-17, 1402/11/28

Registrant information

Name
Mostafa Qorbani
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-01, 1404/03/11

Expected recruitment end date
2026-04-30, 1405/02/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the efficacy of potassium-enriched salt substitutes versus sodium salt on blood pressure control in patients with hypertension: a double-blind randomized clinical trial.

Public title
Effect of potassium-enriched salt versus sodium salt on control of blood pressure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 40 to 65 with confirmed HTN (having measured SBP>= 135mmHg). Patients with blood pressure who are undergoing treatment with blood pressure / anti-hypertensive medication Patients who primarily consume home-cooked meals Participants with written informed consent from both themselves and all their households
Exclusion criteria:
Patients using potassium-sparing diuretics, taking potassium supplements, or with any known acute or chronic kidney disease (CKD) are excluded from the study.
Age
From **40 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **500**
Randomization (investigator's opinion)
Randomized
Randomization description
The Permutation Block Randomization method is employed to allocate patients into two groups: intervention and control. The website www.sealedenvelope.com is utilized to generate the randomization blocks, with block sizes set at 4 and 6. The individual (patient) serves as the unit of randomization. Concealment of the randomization sequence is carried out by a person other than the members of the research, following the randomization list created by www.sealedenvelope.com. Sealed opaque letter envelopes are employed for concealment.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding will be implemented for both the patient and the outcome assessor. Participants in the intervention and control groups will receive similar salt packs. Once a patient meets the study criteria, a third person, who is not a member of the research team and is responsible for random allocation and concealment, will assign the individual to either the intervention or control group. This allocation will be determined based on the contents of a sealed envelope, and the corresponding package will be provided. As a result, the person evaluating the results will be kept unaware of the participant's group assignment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
Deputy of Research and Technology, Alborz University of Medical Sciences Alborz, Safarian Street, 45-Meter Golshahr
City
Karaj
Province
Alborz
Postal code
3198764653
Approval date
2024-01-13, 1402/10/23
Ethics committee reference number
IR.ABZUMS.REC.1402.293

Health conditions studied

1

Description of health condition studied
Hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description

the mean of systolic blood pressure

Timepoint

The measurement is done at the beginning of the study (before the start of the intervention) and at the end of the study (6 months after the intervention) after consuming salt instead of sodium.

Method of measurement

Mercury sphygmomanometer

2

Description

The mean of diastolic blood pressure

Timepoint

The measurement is done at the beginning of the study (before the start of the intervention) and at the end of the study (6 months after the intervention) after consuming salt instead of sodium.

Method of measurement

Mercury sphygmomanometer

3

Description

The mean of blood pressure

Timepoint

The measurement is done at the beginning of the study (before the start of the intervention) and at the end of the study (6 months after the intervention) after consuming salt instead of sodium.

Method of measurement

Mercury sphygmomanometer

Secondary outcomes

1

Description

The mean of 24-hour sodium excretion

Timepoint

The measurement is done at the beginning of the study (before the start of the intervention) and at the end of the study (3 and 6 months after the intervention) after consuming salt instead of sodium

Method of measurement

Urine test

2

Description

The mean of 24-hour potassium excretion

Timepoint

The measurement is done at the beginning of the study (before the start of the intervention) and at the end of the study (3 & 6 months after the intervention) after consuming salt instead of sodium

Method of measurement

Urine test

3

Description

Urinary sodium to potassium ratio

Timepoint

The measurement is done at the beginning of the study (before the start of the intervention) and at the end of the study (3 & 6 months after the intervention) after consuming salt instead of sodium

Method of measurement

The result of dividing the sodium and potassium ratio of urine

4

Description

Serum creatinine

Timepoint

The measurement is done at the beginning of the study (before the start of the intervention) and at the end of the study (3 & 6 months after the intervention) after consuming salt instead of sodium.

Method of measurement

Blood test

5

Description

Attitude of using regular salt or salt substitute

Timepoint

The measurement is done at the beginning of the study (before the start of the intervention) and at the end of the study (3 & 6 months after the intervention) after consuming salt instead of sodium

Method of measurement

Questionnaire

6

Description

Number/percent of individuals who develope hyperkalemia and hypokalemia

Timepoint

The measurement is done at the beginning of the study (before the start of the intervention) and at the end of the study (3 & 6 months after the intervention) after consuming salt instead of sodium

Method of measurement

Biochemical test

7

Description

Occurrence of CVD events such as TIA, cardiovascular accidents, occurrence/reoccurrence of strokes and reoccurrence of hypertensive crisis

Timepoint

The measurement is done at the beginning of the study (before the start of the intervention) and at the end of the study (3& 6 months after the intervention) after consuming salt instead of sodium

Method of measurement

Questionnaire

8

Description

Acceptability, usage, tolerance and taste of the blended salt and attitudes

Timepoint

The measurement is done at the beginning of the study (before the start of the intervention) and at the end of the study (3&6 months after the intervention) after consuming salt instead of sodium

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention Group: Patients are provided with a sodium salt substitute containing 70% sodium and 30% potassium chloride. They are instructed that using potassium salt is equivalent to using sodium salt and can be employed for daily cooking and other routine uses.

Category

Treatment - Other

2

Description

Control Group: Patients receive normal salt (100% sodium chloride) and are instructed to continue using this salt as usual for their daily cooking and other daily uses.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Rajaee Hospital

Full name of responsible person
Alireza Dehghan Nayeri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Karaj University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
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Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data will be available on reasonable request.
When the data will become available and for how long
Data will be available on reasonable request after submitting papers
To whom data/document is available
Data will be available on reasonable request.
Under which criteria data/document could be used
Data will be available on reasonable request.
From where data/document is obtainable
Data will be available on reasonable request from corresponding author.
What processes are involved for a request to access data/document
Data will be available on reasonable request.
Comments